

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC.,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION

MDL NO. 2327

THIS DOCUMENT RELATES TO ALL
WAVE 3 CASES IDENTIFIED IN
EXHIBIT A TO DEFENDANTS' MOTION

**PLAINTIFFS' RESPONSE TO MOTION AND MEMORANDUM TO EXCLUDE
CERTAIN GENERAL OPINIONS OF BOBBY SHULL, M.D.**

Plaintiffs hereby submit *Plaintiffs' Response to Motion and Memorandum to Exclude Certain General Opinions of Bobby Shull, M.D.* and in support of this Response, Plaintiffs state as follows:

I. INTRODUCTION

Robert Shull, M.D. (also referred to as “Bobby” or “Bob” and hereinafter “Dr. Shull”) provided a report on Defendant’s Prolift and Prolift +M products (hereinafter the “Prolift Report”).¹ Dr. Shull is qualified and experienced in the fields of obstetrics and gynecology; he graduated from Tulane University School of Medicine in 1968 and completed his internship and residency at the University of Virginia. *See Curriculum Vitae*, attached as Ex. A to Ex. 1. In addition to having received numerous honors, awards, and serving on various committees and boards, Dr. Shull has been involved in 12 research projects; authored or co-authored 39 peer reviewed publications; authored or co-authored four (4) non-peer reviewed publications; drafted numerous book chapters, abstracts and discussions; and conducted various lectures and

¹ For ease of reference, the Prolift Report is attached hereto as **Exhibit 1**.

presentations. *See id.* Dr. Shull is unquestionably qualified by education, training, skill, and experience to provide the opinions set forth in the Prolift Report, opinions which are based upon sound methodology and proper application of sound methodology; and as such, Dr. Shull's proffered opinions pass scrutiny under a *Daubert* analysis.

Defendants filed a Wave 1 *Daubert* motion to exclude certain of Dr. Shull's opinions. On September 1, 2016, the Court ruled on Defendants' prior-motion. *See Exhibit 2.* Defendants' instant Motion recycles nearly identical arguments made in their Wave 1 briefing and are based on the same expert report proffered by Dr. Shull and the same deposition transcripts utilized in Wave 1. As such, Plaintiffs submit that Defendants should have simply incorporated their Wave 1 briefing with regard to Dr. Shull. Without novel arguments, a revised report, or new deposition testimony, there is no readily apparent reason as to why the Court should rule differently than in Wave 1. Notwithstanding, Plaintiffs' response is set forth below.

II. ARGUMENT

Defendants, in their Motion, incorporate by reference the standard of review for *Daubert* motions as set forth by this Court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D. W. Va. 2014). Plaintiffs agree that this Court's expression of the *Daubert* standard as set forth in *Huskey* is the proper standard of review.

A. The Court Should Allow Dr. Shull To Testify About The Specific Risks Of Implanting Mesh And Whether Those Risks Appeared On The Relevant IFU.

Defendants argue that: "That Court should exclude Dr. Shull's warnings opinions, because he is not qualified and certain of his opinions are irrelevant." Defs.' Mot. at 2. This argument is nearly identical, and identical in all material ways, to the argument presented by Defendants in Wave 1. *Compare* Defs.' Wave 1 *Daubert* [Dkt. 2055 at 10-11] *with* Defs.' Wave 3 *Daubert* [Dkt. 2808 at 2-4]. As such, the Court should rule no differently than it did the first time. Therefore,

Plaintiffs incorporate their original Wave 1 response to Defendants' warnings argument. *See* Plaintiffs' Response [Dkt. 2150 at 12, 16-17]. For these same reasons, Dr. Shull should be allowed to testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU. *See* Ex. 2 at 8.

B. Dr. Shull's Opinions On Mesh Properties Should Not Be Excluded.

Defendants argue that: "The Court should preclude Dr. Shull from suggesting that other synthetic mesh devices have fewer complications, because his opinions are irrelevant and/or unreliable." Defs.' Mot. at 4. Again, Defendants are recycling their Wave 1 briefing and acknowledge as much: "Ethicon challenged this same assertion in its Wave 1 briefing on the basis that it perceived that Dr. Shull was unreliably suggesting that a device with larger pore, lighter weight mesh would offer a safer, feasible alternative to Prolift." *Id.* The Court denied Defendants' Motion on this point in Wave 1. *See* Ex. 2 at 6-7. The Court noted: "In its attempt to demonstrate a logical fallacy, Ethicon has created its own." Ex. 2 at 7. Notwithstanding, Defendants assert the identical "logical fallacy" argument in their instant Motion as presented in their Wave 1 brief. *Compare* Defs.' Wave 1 *Daubert* [Dkt. at 8-9] *with* Defs.' Wave 3 *Daubert* [Dkt. 2808 at 4-6]. As such, Plaintiffs incorporate their Wave 1 response here. *See* Plaintiffs' Response [Dkt. 2150 at 4-7, 16]. For these same reasons, Dr. Shull's opinions related to mesh properties should not be excluded. *See* Ex. 2 at 6-7.

C. Defendant Raises No Argument With Regard To "Design" Opinions, And Therefore, Their Motion In This Regard, Should Be Denied.

It is unclear what argument is being raised by Defendants with regard to Dr. Shull's purported "design" opinions. Defendants argue: "In, adjudicating Ethicon's challenge to these same opinions in the Wave 1 cases, the Court indicated that it did not construe Dr. Shull's reports as 'express[ing] any opinions about the process of designing a product' . . . Because Dr. Shull's

reports in this wave of cases are identical to his Wave 3 cases, the Court should make the same finding here.” Defs.’ Mot. at 7 (internal citation omitted). Fine, Plaintiffs agree. Defendants further request: “Alternatively, Ethicon respectfully requests that the Court preclude Dr. Shull from providing such opinions on the basis that he is unqualified to do so.” *Id.* But, the Court has already ruled that Dr. Shull is not expressing “any opinions about the process of designing a product,” Plaintiffs agree with the Court’s observations; and therefore, Dr. Shull’s qualifications on this issue need not be examined. Plaintiffs submit the Court need not alter its prior ruling on this issue, thereby denying Defendants’ Motion in this regard. *See* Ex. 2 at 7-8.

D. Defendants’ Arguments Regarding The Duties Of A Medical Device Manufacturer Are Identical In All Material Ways To Their Wave 1 Arguments, And The Court Should Rule The Same As It Did In Wave 1.

Defendants seek exclusion of a variety of Dr. Shull’s opinions, real or imagined, related to the duties of a medical device manufacturer. Defs.’ Mot. at 7-11. These arguments are identical in all material ways to the arguments presented in Defendants’ Wave 1 Briefing. *Compare* Defs.’ Wave 1 *Daubert* [Dkt. 2055 at 3-7] with Defs.’ Wave 3 *Daubert* [Dkt. 2808 at 7-11]. As such, Plaintiffs incorporate their Wave 1 response here. *See* Plaintiffs’ Response [Dkt. 2150 at 11-16]. For these same reasons, Dr. Shull’s opinions related to duties of a medical device manufacturer, to the extent they exist, should be subject to the Court’s ruling as set forth in Wave 1. *See* Ex. 2 at 9-13 (under heading “Recurring Issues”).

E. Defendants’ Arguments Related To Prolene Soft Properly Belong In A Case-Specific Motion, And Therefore, Should Be Denied.

Defendants raise an argument that properly belongs in a case-specific motion rather than a general *Daubert* motion: “Although one of the Plaintiffs in Exhibit A to Defendants’ motion, Bonita Taylor, designated Dr. Shull a general causation expert, she was not implanted with any of these devices.” Defs.’ Mot. at 11. It is not clear why Defendants raised this argument in their

general *Daubert* brief as it properly belongs in a case-specific motion so that Ms. Taylor may address this argument directly. Given the orders issued on these cases related to briefing of *Daubert* motions, due process concerns militate against any other outcome. For these reasons, Plaintiffs request Defendants' argument in this regard be denied.

F. The Remainder Of Defendants' Arguments Are Moot.

Defendants argue: "Finally, consistent with its prior rulings, the Court should preclude Dr. Shull from: . . . (listing a host of subjects with no supporting briefing)." Defs.' Mot. at 11-12. To the extent the Court can discern whether Defendants' arguments are different than those presented in their Wave 1 briefing (Plaintiffs are unable as they are simply presented in a laundry list fashion), the Court has at least addressed most of these issues in its Wave 1 Order on Dr. Shull.² *See* Ex. 2 at 13. As such, Plaintiffs agree that if the Court rules on these arguments, they should be consistent with the Court's prior order on Dr. Shull. *Id.*

III. CONCLUSION

For all of the foregoing reasons and those expressed in response to Defendants' Wave 1 briefing, Plaintiffs respectfully request Defendants' Motion be denied as described herein.

Dated: October 7, 2016

Respectfully submitted,

By: /s/ Aimee H. Wagstaff

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² Defendants also argue for exclusion of testimony "about a medical condition that a Plaintiff's medical expert has not competently testified that the Plaintiff has sustained or likely will sustain." Defs.' Mot. at 11. Again, this type of argument belongs in a case-specific motion, and it is unclear why Defendants have raised it here. In any event, this request should be denied.

CERTIFICATE OF SERVICE

I hereby certify that on October 7, 2016, a true and correct copy of *Plaintiffs' Response to Motion and Memorandum to Exclude Certain General Opinions of Bobby Shull, M.D.* was served via electronic mail with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the CM/ECF counsel of record.

Dated: October 7, 2016

Respectfully submitted,

By: /s/ Aimee H. Wagstaff